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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,465	10/16/2006	Vincent Pongpairochana	5001-1255	7176
466 YOUNG & TH	7590 11/12/200 OMPSON	EXAMINER		
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Suite 500 ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER
			4158	
			MAIL DATE	DELIVERY MODE
			11/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/589,465	PONGPAIROCHANA ET AL.			
Office Action Summary	Examiner	Art Unit			
	JASON FLICK	4158			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>20 Mar</u> This action is FINAL . 2b)⊠ This Since this application is in condition for alloward closed in accordance with the practice under Expression in the practice of the practice	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1-32 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-32 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examine 10) ☐ The drawing(s) filed on 14 August 2006 is/are: Applicant may not request that any objection to the ore Replacement drawing sheet(s) including the correction.	vn from consideration. r election requirement. r. a)⊠ accepted or b)□ objected the drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date See Continuation Sheet	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite			

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :08/14/2006; 01/12/2007; 03/20/2007.

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the European Patent Office on 02/18/2004. It is noted, however, that applicant has not filed a certified copy of the 04100847.9 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 3. Claims 1, 2, 4-6, 22 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Hjertman et al. (patent number 6,599,272).
- 4. [Claim 1] Hjertman teaches a hand-held, electronically controlled injection device (figure 2b, item 200) capable of injecting preset doses of liquid medication, comprising a housing (figure 1a, item 110) which is adapted for receiving a medication container (figure 1a, item 120) containing the liquid medication, and has a contact surface (figure 1a, item 111) for contacting a patient's skin, characterized by comprising first actuator

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means (figure 1a, item 133) for moving said medication container within said housing to and from said contact surface (column 15, lines 65-67; column 16, line 1).

- 5. [Claim 2] Hjertman teaches the limitations of claim 1, upon which claim 2 depends. In addition, Hjertman discloses the contact surface of the housing comprising a through opening (figure 2b, item 222) for receiving a needle assembly (figure 2a, item 220) comprising a needle (figure 2a, item 223) and at least one needle housing (figure 2a, item 221) fitted to said needle; and by comprising releasable retaining means (figure 2b, items 234 and 235) for locking said needle housing in a predetermined position engaging said opening, both during displacement of said medication container (figure 2a, item 226) towards said contact surface from a first operating position withdrawn inside said housing to a second operating position connected to said needle, and during reverse displacement of said medication container from said second to first operating position to permit automatic withdrawal of said needle from said needle housing (column 19, lines 6-38).
- 6. [Claim 4] Hjertman teaches the limitations of claim 2, upon which claim 4 depends. In addition, Hjertman discloses a locking lever (figure 1a, item 130) movable between a lock configuration in which a respective work portion (figure 1a, item 149) projects inside said opening to interact with said needle housing (figure 1a, item 121), and a release configuration, in which said work portion is located outside said opening.
- 7. [Claim 5] Hjertman teaches the limitations of claim 4, upon which claim 5 depends. In addition, Hjertman discloses a locking lever (figure 1a, item 130) which is loaded elastically (figure 1a, item 133) into the lock configuration; and in that push

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means (figure 1a, item 131) are provided to set said locking lever to said release configuration at least in said first operating position of said medication container (figure 1a, item 120).

- 8. [Claim 6] Hjertman teaches the limitations of claim 5, upon which claim 6 depends. In addition, Hjertman discloses push means comprising cam means (figure 1c, item 150) interposed between said locking lever (figure 1c, item 142) and a support (figure 1c, item 128) for supporting said medication container (figure 1c, item 120') and which is movable to and from said contact surface (figure 1c, item 111').
- 9. [Claim 22] Hjertman teaches the limitations of claim 1, upon which claim 22 depends. In addition, Hjertman discloses a device comprising a second actuator means (figure 2d, item 225) which is activated selectively to force the liquid medication contained in said medication container through the patient's skin.
- 10. [Claim 28] Hjertman teaches the limitations of claim 22, upon which claim 28 depends. In addition, Hjertman discloses a device characterized by comprising injection control button means (figure 3, item 330), said button means successively activating said first actuator means (figure 1a, item 133) to move the assembly defined by the medication container (figure 1a, item 120) and needle (figure 1a, item 123) from the first to the second operating position so that the needle penetrates the patient's skin, and said second actuator means (figure 1a, item 125) to deliver through the patient's skin a preset dose of liquid medication contained in said medication container.

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Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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- 12. Claims 3, 10-13, 15-16 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertman et al. (patent number 6,599,272), in view of Lippe et al. (patent number 6,171,276).
- 13. [Claim 3] Hjertman teaches the limitations of claim 2, upon which claim 3 depends. Hjertman is silent on a presence sensor means which generates a presence signal to activate said first actuator means upon said needle housing engaging said opening. However, Lippe discloses an automated delivery device comprising a presence sensor means (figure 1a, item 11) utilized to activate a first actuator means (figure 1a, item 7) upon said needle housing engaging said opening (column 16, lines 22-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman with the presence sensor taught by Lippe in order to provide means of detecting a secure connection between the device and the needle housing.
- 14. [Claim 10] Hjertman teaches the limitations of claim 2, upon which claim 10 depends. Hjertman is silent on a releasable retaining means comprising at least one releasable member. However, Lippe discloses at least one releasable retaining member (figure 3b, items 33 and 34) actuated by said needle housing upon insertion of said needle housing into said opening, capable of retaining said needle housing at least during said displacement of said medication container from said first to said second operating position (column 17, lines 35-54). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by

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Hjertman with the releasable retaining member taught by Lippe in order to provide a means of making the needle assembly detachable from the medication container.

- 15. [Claim 11] Hjertman and Lippe teach the limitations of claim 10, upon which claim 11 depends. In addition, Lippe discloses releasable retaining means which further comprise abutment surfaces (figure 2b, items 21 and 22) for limiting the insertion of said needle housing into said opening and for retaining said needle housing during said reverse displacement of said medication container from said second to said first operating position.
- 16. [Claim 12] Hjertman and Lippe teach the limitations of claim 10, upon which claim 12 depends. In addition, Lippe discloses sensor means (figure 2b, items 21 and 22; column 9, lines 34-48) for sensing actuation of said releasable retaining member.
- 17. [Claim 13] Hjertman and Lippe teach the limitations of claim 12, upon which claim 13 depends. In addition, Hjertman discloses a means of reversing displacement (needle retraction spring) of the medication container (column 11, lines 56-64).
- 18. [Claim 15] Hjertman teaches the limitations of claim 1, upon which claim 15 depends. Hjertman is silent on a medication and needle assembly characterized by a needle support and holder. However, Lippe discloses a needle support (figure 3b, item 30) which is provided with an elastic flange (figure 3b, items 33 and 34) for connection of said needle support to the end of the medication container unit. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman with the needle support and flange taught by Lippe in order

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to provide a means of making the needle assembly detachable from the medication container.

- 19. [Claim 16] Hjertman teaches the limitations of claim 1, upon which claim 16 depends. Hjertman is silent on a sensor means for detecting a connection between a needle and a medication container. However, Lippe discloses a sensor means (figure 1a, item 11) for detecting a proper connection of the needle to the medication container (column 16, lines 16-18). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman with the sensor taught by Lippe in order to provide a means of ensuring a connection between the needle and the medication container.
- 20. [Claim 31] Hjertman teaches a medication injection device comprising means for receiving a medication container (figure 1a, item 120) an end (figure 1a, item 122) of which is connectable to a needle (figure 1a, item 123), control means (figure 3, item 330) and means (figure 3, item 325), controlled by said control means, for pushing liquid medication contained in said medication container out of said medication container through said needle. Hjertman is silent on a sensor means for detecting a connection between a needle and a medication container. However, Lippe discloses a sensor means (figure 1a, item 11), connected to said control means (figure 3, item 330) for detecting a proper connection of the needle to the medication container (column 16, lines 16-18). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman with the sensor taught by Lippe

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in order to provide a means of ensuring a connection between the needle and the medication container.

- 21. Claims 7-9 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertman et al. (patent number 6,599,272), in view of Baba et al. (PGPub 2005/0090781).
- 22. [Claim 7] Hjertman teaches the limitations of claim 2, upon which claim 7 depends. Hiertman is silent on means of removing the needle from the medication container, wherein the removing means comprises a stop means which are activated selectively in a third operating position of said medication container, close to said second operating position, to lock the needle and disconnect the needle from the medication container as the medication container moves into the first operating position. However, Baba discloses a means of removing (figure 10, item 58) the needle from the medication container, wherein the removal means comprises a stop means (figure 10, item 58a), which are activated selectively in a third operating position of the medication container, to lock and disconnect the needle from the medication container as the medication container is moved into a first operating position. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman with the needle removal and stopping structures taught by Baba in order to provide a more effective means for interchanging the needle with the device housing.
- 23. [Claim 8] Hjertman and Baba teach the limitations of claim 7, upon which claim 8 depends. In addition, Hjertman discloses a device with a third operating position which

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is located on the opposite side of the second operating position with respect to the first operating position in the traveling direction of the medication container (figures 1a, 1b, and 1c).

- 24. [Claim 9] Hjertman and Baba teach the limitations of claim 7, upon which claim 9 depends. In addition, Baba discloses a needle assembly (figure 10) comprising a needle support (figure 10, item 82) supporting said needle (figure 10, item 51) in projecting manner and connectable to one end (figure 10, item 64) of said medication container (figure 10, item 52), characterized in that, in said third operating position of said medication container, said work position of said locking lever (figure 10, item 58) is interposable between said medication container and said needle support to define said stop means (figure 10, item 58a).
- 25. [Claim 29] Hjertman teaches the limitations of claim 28, upon which claim 29 depends. Hjertman is silent on a skin sensor to detect interaction between the contact surface and a patient's skin. However, Baba discloses a skin sensor (figure 23, item 140) capable of generating a signal to activate said control button upon interaction between the contact surface and the patient's skin. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman with the skin sensor taught by Baba in order to provide a more efficient means of confirming proper contact between a patient's skin and the injection device.
- 26. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertman et al. (patent number 6,599,272), in view of Baba et al. (PGPub 2005/0090781), in further view of Kovelman et al. (PGPub 2007/0142776).

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27. [Claim 30] Hjertman and Baba teach the limitations of claim 29, upon which claim 30 depends. In addition, Baba discloses a selecting means for setting the dose of liquid medication to be injected into the patient (figure 1, item 56). Hjertman and Baba are silent on a means for controlling the speed of injecting. However, Kovelman teaches a means for selecting the speed at which the medication container moves towards the contact surface as the needle penetrates the patient's skin (pages 9-10, paragraph [0120]; see also figures 48a-48d). It would have been obvious to one of ordinary skill in the art to modify the structure taught by Hjertman and Baba with the means for controlling injection speed taught by Kovelman in order to provide increased control over the injection process.

- 28. Claims 23-27 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertman et al. (patent number 6,599,272), in view of Vanderveen (PGPub 2005/0107923).
- 29. [Claims 23 and 32] Hjertman teaches the limitations of claim 22, upon which claim 23 depends. Hjertman discloses an actuator assembly (figure 2d, item 271) and a push member (figure 2d, item 225) driven by the actuator assembly, which can be moved axially from a retracted position, located outside the medication container (figure 2d, item 220) and push the liquid medication out of the container through a needle (figure 2d, item 223) and then return to a retracted position. Hjertman also teaches a door locking mechanism (column 7, lines 43-51). Hjertman is silent on door with a door opening mechanism. However, Vanderveen discloses a fluid infusion device comprising a door (figure 3, item 50) which, in its open position, permits insertion

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/removal of a medication container (figure 3, item 66) into/from a housing (figure 3, item 22), a door opening mechanism (figure 3, item 52) for opening/closing said door and a lock mechanism (page 4, paragraph [0035]) for locking at least part of the door opening mechanism. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman with the device door, lock, and opening mechanism taught by Vanderveen in order to provide a means of securing medication within the injection device.

- 30. [Claim 24] Hjertman and Vanderveen teach the limitations of claim 23, upon which claim 24 depends. In addition, Hjertman discloses a device comprising a lock mechanism (column 7, lines 43-51) capable of locking a door opening button (figure 3, item 330).
- 31. [Claim 25] Hjertman and Vanderveen teach the limitations of claim 24, upon which claim 25 depends. In addition, Hjertman discloses a lock mechanism comprising a first lever (claim 44) which, in a rest position, locks said door opening button (figure 3, item 330) and which is actuated by said push member (figure 3, item 325) during retraction to unlock said door opening button (column 22, line 3-20).
- 32. [Claim 26] Hjertman and Vanderveen teach the limitations of claim 25, upon which claim 26 depends. In addition, Hjertman discloses a locking mechanism further comprising a part (figure 3, item 318) movable in the direction of displacement of said push member (figure 3, item 325) and which, in a rest position, is out of contact with said first lever (figure 3; claim 44) and, during retraction, comes into contact with said first lever (see figure 3).

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33. [Claim 27] Hjertman and Vanderveen teach the limitations of claim 23, upon which claim 27 depends. In addition, Hjertman discloses a device comprising a door opening button (figure 3, item 330) movable in the direction of displacement of the push member (figure 3, item 325), a second lever (figure 3, item 318) actuated by said door opening button (figure 3, item 330), a locking member (figure 3, item 327) movable in said direction, actuated by said second lever (figure 3, item 318) and having a first flange (figure 3, item 319), and a medication container holder (figure 3, item 350) for holding said medication container (figure 3, item 320) inside said housing (figure 3, item 310), said medication container holder (figure 3, item 350) having a second flange (figure 3, item 319') designed to cooperate with said first flange (figure 3, item 319) and being pivotable with said door (figure 3, item 315) from a closed to an open position of said door (figure 3, item 315) when said second flange (figure 3, item 319') is released by said first flange (figure 3, item 319).

- 34. Claims 14, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertman et al. (patent number 6,599,272), in view of Lippe et al. (patent number 6,171,276), in further view of Baba et al. (PGPub 2005/0090781).
- 35. [Claim 14] Hjertman and Lippe teach the limitations of claim 10, upon which claim 14 depends. Hjertman and Lippe are silent on a removing means for removing a needle from a medication container. However, Baba discloses a means of removing (figure 10, item 58) the needle from the medication container, wherein the removal means comprises a stop means (figure 10, item 58a), which is capable of being activated in a second operating position of the medication container, to retain and

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disconnect the needle from the medication container as the medication container is moved from a second to a first operating position. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman and Lippe with the needle removal and stopping structures taught by Baba in order to provide a more effective means for interchanging the needle with the device housing.

- 36. [Claims 17 and 18] Hjertman and Lippe teach the limitations of claim 16, upon which claims 17 and 18 depend. Hjertman teaches a medication container capable of being of various sizes and shapes (column 15, lines 62-67). Hjertman and Lippe are silent on a device comprising an optical sensor. However, Baba teaches a device employing optical sensors capable of detecting the proper connection of a needle with a medication container (paragraphs [0022] and [0023]; see also figure 30, items 419a and 419b). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman and Lippe with the optical sensors taught by Baba in order to provide an alternative means of detecting a proper connection between the needle and the medication container of the injection device.
- 37. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertman et al. (patent number 6,599,272), in view of Lippe et al. (patent number 6,171,276), in view of Baba et al. (PGPub 2005/0090781), in further view of Spohn et al. (PGPub 2003/0065287).
- 38. [Claims 19 and 20] Hjertman, Lippe, and Baba teach the limitations of claim 17, upon which claims 19 and 20 depend. Hjertman, Lippe, and Baba are silent on a

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second sensor means capable of detecting a partial connection of the needle to the medication container. However, Spohn discloses a second sensor means comprising an optical transmitter and receiver (figure 2a, items 120a, 120b, 140a, and 140b) capable of detecting partial connection of the needle to the medication container (page 5, paragraphs [0065] and [0067]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman, Lippe, and Baba with the plurality of optical transmitters and receivers taught by Spohn in order to provide a means of detecting a partial or full connection between the needle and the medication container of the injection device.

- 39. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertman et al. (patent number 6,599,272), in view of Lippe et al. (patent number 6,171,276), in further view of Spohn et al. (PGPub 2003/0065287).
- 40. [Claim 21] Hjertman and Lippe teach the limitations of claim 16, upon which claim 21 depends. Lippe discloses a needle support (figure 3b, item 30) which is provided with an elastic flange (figure 3b, items 33 and 34) for connection of said needle support to the end of the medication container unit. Hjertman and Lippe are silent on optical sensors and a reflective portion of the elastic flange. However, Spohn discloses a second sensor means comprising an optical transmitter and receiver (figure 2a, items 120a, 120b, 140a, and 140b) capable of detecting partial connection of the needle to the medication container (page 5, paragraphs [0065] and [0067]). Spohn also teaches reflective surfaces (figure 2a, items 23a and 23b) provided on the surfaces of flanges capable of reflecting an optical transmission towards an optical receiver and configured

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such that partial or complete connection is detected between a needle and a medication container (page 5, paragraph [0065]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Hjertman and Lippe with the optical transmitter/receiver and reflective surfaces taught by Spohn in order to provide a means of detecting a partial or full connection between the needle and the medication container of the injection device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./ Examiner, Art Unit 4158 11/06/2008

/Fenn C. Mathew/ Primary Examiner